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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,367	05/22/2007	Christoph Marcol Tang	06-451	1855

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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,367	TANG ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21-23 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19,21-23,25-31* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *notice to comply*.

Lack of Unity of Invention

Claims 1-19,21-23 and 25-31 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, and 21 drawn to a plurality of species of methods for identifying a polypeptide or polynucleotide of a microorganism, the polypeptide and polynucleotide being associated with an immune response in an animal.

Group II, claim(s) 16-18, 22, 25,26-28 drawn to a plurality of polypeptide antigens of a pathogen or a plurality of polynucleotides that encode for SEQ ID NOs 2,4,6,8,10,12,14,16, 18,20,22, 24, 26, 28,30,32, 34,36,38,40,42,44,46,48,50,52,54,56 and variants, fusions and fragments thereof.

Group III, claim(s) 19 drawn to a method of vaccinating an individual.

Group IV, claim(s) 23, drawn to a mutant microorganism that is not killed by antibodies directed against the microorganism because of the mutation in the microorganism.

Group V, claim(s) 29, drawn to a plurality of species of methods of recombinantly expressing a polypeptide of SEQ ID NOs 2,4,6,8,10,12,14,16,18,20,22,24,26,28,30,32, 34,36,38,40,42,44,46,48,50,52,54,56 and variants, fusions and fragments thereof.

Group VI, claim(s) 30, drawn to a plurality of species of methods of chemically synthesizing a polypeptide SEQ ID NOs 2,4,6,8,10,12,14,16,18,20,22,24,26,28,30,32, 34,36,38,40,42,44,46,48,50,52,54,56 and variants, fusions and fragments thereof.
.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Li et al (1997) describes the first appearing invention directed to a method for identifying a polypeptide, the method comprising the steps of

providing, contacting, selecting, identifying the gene and identifying the polypeptide encoded by the gene; these 5 methods steps are described by Li et al (see Figure 5, plurality of mutant microorganisms) contacted with antiserum from an animal (figure 5 Ledger narrative), wherein the mutant strains are not killed to the same degree as strains that do not evidence the mutation (wild-type strain A909 showed a higher Log decrease in the number of colony forming units thus showing greater killing by the antibodies and complement assay), wherein the mutants that survived the opsonophagocytic killing were selected for further analysis (see page 13255, col. 2, paragraph 2), and gene identified was bca gene and the polypeptide identified was alpha C protein. The first appearing claimed invention does not make a contribution over the prior art, therefore the claimed inventions are not so linked as to evidence unity of invention. The claimed inventions Lack Unity of Invention in light of the description and disclosure of Li et al (1997) who describes the first appearing special technical feature, the first appearing special technical feature not making a contribution over the prior art. Li et al anticipates the first claimed invention.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I: Species I: a pathogenic microorganism (claim 2)

Species II: the microorganism naturally grows in the animal used to obtain an immune response (claim 3)

Species III: the microorganism is a bacterium (see claim 5)

Species IV: the microorganism is Neisseria menigitidis (claim 6)

Species V: a homologous polypeptide from a related microorganism (claim 13).

Group II: each claimed species of polypeptide/polynucleotide is identified by a separate SEQ ID NO (claim 25): SEQ ID NOs 2,4,6,8,10,12,14,16, 18,20,22, 24, 26, 28,30,32, 34,36,38,40,42,44,46,48,50,52,54,56 and variants, fusions and fragments thereof. (select a single SEQ ID NO for the polypeptide and the polynucleotide that encodes it)

Group V: each claimed species of polypeptide identified by a separate SEQ ID NO defines a separate species of method of recombinantly expressing the coding polynucleotide to make the polypeptide (claim 29). SEQ ID NOs 2,4,6,8,10,12,14,16, 18,20,22, 24, 26, 28,30,32, 34,36,38,40,42,44,46,48,50,52,54,56 and variants, fusions and fragments thereof. (select a single SEQ ID NO for the polypeptide and the polynucleotide that encodes it)

Group VI: each claimed species of polypeptide identified by a separate SEQ ID NO defines a separate species of method of chemically synthesizing a polypeptide (claim 30) of SEQ ID NOs 2,4,6,8,10,12,14,16, 18,20,22, 24, 26, 28,30,32, 34,36,38,40,42, 44,46,48, 50,52, 54,56 and variants, fusions and fragments thereof. (select a single SEQ ID NO for the polypeptide and the polynucleotide that encodes it)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner: See list of species provided above.

The following claim(s) are generic: claim 1 of Group I is generic for identifying a polypeptide in any microorganism.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Li et al describe the first species of claimed species of group I, specifically a pathogenic microorganism polypeptide is identified in group B streptococcus, a human pathogenic microorganism. Therefore the first appearing species of invention is anticipated by Li et al, and the claimed species of invention are not so linked by a special technical feature that makes a contribution over the prior art. Additionally, the claimed species differ in chemical structure, function and biological effect based upon the different binding specificities of the antibodies directed against the microorganism's polypeptide that present differing structures for stimulating and reacting with antibodies.

1. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. At page 15, line 1 [PG-Pub paragraph 0053] a hyperlink is recited; it should be removed.

Specification/Sequence Requirements

This application contains sequence disclosures at page 22 (lines 20-22), and pages 29-45 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2). SEQ ID NOs should be assigned and/or inserted next to the sequence(s) they identify at each occurrence of the sequence(s) in the Specification, drawings/brief description of the drawings and claims.

3. However, the fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below: Nucleic acid sequences of 10 or more nucleotides and amino acid sequences of 4 or more residues need to be designated with a sequence identifier. Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth above. Failure to fully comply with ***both*** these requirements in the time period set forth in this office action will be held non-responsive.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
July 10, 2009

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645